K102437

510(k) Summary

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SEP 24 2010

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Date Prepared: September 24, 2010

DEVICE INFORMATION

Trade/Proprietary Name:	GMK® Total Knee System- Revision
Common Name	Total Knee Prosthesis
Classification Name:	Knee joint patellofemorotibial metal/polymer/metal semiconstrained cemented prosthesis,
Classification:	Class II, 21 CFR 888.3560
Product Code:	JWH

Predicate Device: K090988 GMK® Total Knee System (Medacta International), cleared July 10, 2009

Product Description:
The modification to the original Medacta GMK® (Global Medacta Knee) Total Knee System is a line extension to include the GMK® Revision femoral components (STD and PS), extension stems with offset adaptors, distal and posterior femoral wedges and tibial wedges.
GMK® Revision femoral components are based on the design of the GMK® Primary femoral components in the original 510(k) submission K090988. The GMK® Revision differs from GMK® Primary by an internal box that allows attachment of the extension stem and the femoral pegs are replaced by two threaded holes to attach femoral wedges.

GMK® Revision femoral components are available in two versions, standard and posterior stabilized femurs, left and right from size 1 to 6. The femoral posterior wedges include sizes 1- 6 with a thickness of 5mm and 10mm while the femoral distal wedges are available in the same size range (1- 6), in thicknesses of 4mm, 8mm and 12mm. Distal and posterior wedge screws are offered in 4mm, 8mm, and 12mm. GMK® Revision femoral components work with the same Tibial baseplates, UC tibial inserts, posterior stabilized tibial inserts and patellas cleared under the original GMK® Total Knee System, K090988.

The offset adaptors are available in 3mm and 5mm and the associated extension stems are offered in diameters of 11mm, 13mm, 16mm, 19mm and 20mm with each being 65mm, 105mm or 150mm in length. The tibial wedges are available in size 1- 6 at a thickness of 5mm or 10mm.

Indications for Use:
The GMK® Total Knee System is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis
- avascular necrosis of femoral condyle
- post traumatic loss of joint configuration
- primary implantation failure.

Tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

Comparison to Predicate Devices
The indications for use for the modified system remain the same as the original 510(k), K090988.

GMK® Revision femoral components are manufactured of Cobalt Chromium Molybdenum (CoCrMo) according to ISO 5832-4:1996, Implants for Surgery-Metallic materials – Part 4: Cobalt-Chromium-Molybdenum Casting Alloy, the same as the GMK® Primary femoral components in the original submission. They have an asymmetric patellar groove (left and right) with different radii of curvature in coronal plane as well as non-parallel anterior and posterior cuts (wedge shape). The GMK® Revision posterior stabilized femoral components are design for use without cruciate ligaments when additional stability is required to prevent subluxation of the femur to the tibia in flexion, same as the GMK® Primary femoral components.

GMK® Revision femoral components are available in two versions, standard and posterior stabilized femurs, left and right from size 1 to 6. The sizes are the

same as GMK® Primary femoral components. The external shape of the GMK® Revision femoral component is identical to that of GMK® Primary. The GMK® Revision differs from GMK® Primary by an internal box that allows attachment of the extension stem and the femoral pegs are replaced by two threaded holes to attach femoral wedges.

GMK® Revision femoral components work with the same Tibial baseplates, UC tibial inserts, posterior stabilized tibial inserts and patellas cleared under the original GMK® Total Knee System, K090988. However, the GMK® Revision femoral components are not used with the standard tibial inserts. These system compatibilities are the same as the original devices, GMK® Total Knee System.

GMK® Revision femoral components are designed to add posterior and/or distal wedges as well as the 3mm offset with extension stems. In addition, tibial wedges, 3mm and 5mm offset with extension stems are designed for use with the same tibial baseplate cleared under the original GMK® Total Knee System, K090988. These additional system compatibilities are new to the original device however there are no new issues of safety and effectiveness.

GMK® Revision offset adaptors, extension stems, wedge screws and tibial wedges are manufactured of titanium alloy (Ti6-Al4-V) according to ISO 5832-3:1996, Implants for Surgery – Metallic materials – Part 3: Wrought titanium 6-aluminum 4-vanadium alloy, the same as the extension stem in the original submission. The offset adaptors are available in 3mm and 5mm and the associated extension stems are offered in diameters of 11mm, 13mm, 16mm, 19mm and 20mm with each being 65mm, 105mm or 150mm in length. This is similar to the extension stem (∅11mm, 64mm) in the original submission. Distal and posterior wedge screws are offered in 4mm, 8mm, and 12mm while the tibial wedges available in size 1- 6 at a thickness of 5mm or 10mm.

GMK® Revision femoral posterior and distal wedges are manufactured from Stainless Steel according to ISO 5832-9:2007 Implants for surgery -- Metallic materials -- Part 9: Wrought high nitrogen stainless steel. The femoral posterior wedges include size 1- 6 with a thickness of 5mm and 10mm while the femoral distal wedges are available in the same size range (1- 6), in thicknesses of 4mm, 8mm and 12mm.

GMK® Revision fixing cylinder for the tibial wedges are manufactured from ultra-high molecular weight polyethylene (UHMWPE) according to ISO 5834-2: 2006, Implants for Surgery – Ultra-High molecular weight polyethylene – Part 2: Moulded Forms, same as the UHMWPE components in the original submission. The GMK® Total Knee System- Revision components' design and technological characteristics are similar to the predicate device. The GMK® Total Knee System- Revision components are packaged and sterilized in the manner as the predicate, the GMK® Total Knee System- Primary.

Performance Testing

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act.

Risk analysis was conducted on the impact of these changes and appropriate design verification and validation was conducted under the company's design controls. The protocols and predefined acceptance criteria were based on the FDA guidance and international standards.

Potential risks identified from the changes were changes in biocompatibility due to new materials and risk of breakage or reduced endurance of interlock strength of the following:

Extension stems and offset adaptors to the femoral components,
Posterior and distal wedges to femoral components.
Extension stems and offset adaptors to tibial baseplate
Tibial wedges to tibial baseplate

Potential risks due to new materials were resolved by using only materials that meet recognized standards and have a long history of acceptable biocompatibility in orthopedic applications. Potential risks due to risk of breakage or reduced endurance of interlock strength of the various new components, extension stems, offset adaptors, femoral wedges, and tibial wedges, were resolved by conducting verification studies that demonstrated that interlocking mechanisms could survive 10 million cycles at physiological loads and had acceptable torsional and disassembly forces. The testing was conducted on the worst case component size and option/design. Testing was conducted according to ASTM F1814-97a Standard Guide for Evaluating Modular Hip and Knee Joint Components, ASTM F897-02:2007 Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws and ASTM F1800-04 Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements. The testing met all acceptance criteria and verifies that performance of the GMK® Total Knee System- Revision is substantially equivalent to the predicate device.

Conclusion:

The results from testing and analysis provided in this submission support the conclusion that the GMK® Total Knee System- Revision is substantially equivalent to its predicate device with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medacta International SA
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SEP 24 2010

Re: K102437
Trade/Device Name: GMK Total Knee System - Revision
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial metal/polymer/metal semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: August 16, 2010
Received: August 26, 2010

Dear Ms. Kennel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Boehm
for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102437

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The tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

Prescription Use __X__ AND/OR Over-The-Counter Use ___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102437